EDISON

Midatech Pharma

Regulatory update

MTX110 receives ODD from the EMA for gliomas

Pharma and biotech

Midatech's lead clinical asset, MTX110, has achieved another regulatory milestone following the decision by the European Medicines Agency (EMA) to grant the drug orphan drug designation for the treatment of gliomas. This includes recurrent glioblastoma (rGBM), diffuse intrinsic pontine glioma (DIPG) and medulloblastoma, currently being targeted by MTX110. ODD should grant Midatech 10 years of market exclusivity on approval, in addition to other incentives such as protocol development assistance and reduced fees. As a reminder, MTX110 already has ODD in DIPG and recently received fast track designation for rGBM by the US FDA.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	DPS (%)	Yield (%)
12/18	1.94	(11.8)	(339)	0.0	N/A	N/A
12/19	0.67	(10.9)	(50)	0.0	N/A	N/A
12/20	0.34	(11.1)	(22.9)	0.0	N/A	N/A
12/21	0.58	(6.1)	(6.8)	0.0	N/A	N/A

Note: *PBT and EPS are normalised.

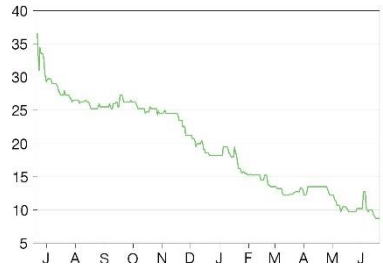
The recent award of ODD by the EMA marks the latest recent regulatory win by the company for its lead clinical asset, MTX110. The EMA grants ODD to therapeutics meeting pre-specified criteria, including treatment of a life-threatening condition and prevalence of a maximum of five in 10,000 in the EU. A key benefit is that, if approved, the drug is likely to receive 10 years of market exclusivity (versus seven years in the US). This essentially means that no other drugs can be approved using the same active ingredient for these indications, significantly enhancing the market opportunity, in our opinion.

As a reminder, MTX110 uses the company's proprietary MidaSolve technology to solubilise the chemotherapy drug panobinostat, which is delivered through a convection-enhanced delivery (CED) system directly to the site of the tumour. The drug recently received fast track designation from the US FDA for rGBM and Midatech has announced plans to initiate a Phase I study targeting this indication in the next few weeks. The primary objectives will be to assess safety and tolerability in patients with rGBM (dose-escalation study estimated to recruit between 10 and 12 patients), but the study will also track preliminary efficacy signals such as progression-free survival. Midatech expects to release preliminary data from the study by Q422.

21 June 2022

Price	**8.75p**
Market cap	**£9m**
Net cash (£m) at end December 2021	10.1
Shares in issue	98.5m
Free float	69%
Code	MTPH
Primary exchange	AIM
Secondary exchange	N/A

Share price performance



Business description

Midatech Pharma is platform-based drug delivery specialist founded in 2000 and listed on the AIM in 2014. Its three technology platforms, Q-Sphera (for sustained release of drugs), MidaSolve (nano inclusion for local delivery) and MidaCore (gold nanoparticles for targeted delivery), are designed to re-engineer and reformulate existing therapeutic drugs with the aim of improving biodistribution and delivery. The realigned focus is now on the Q-Sphera development pipeline and the clinical asset MTX110 (for brain cancer).

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